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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,858	10/06/2000	Peter Beetham	PM49317/272063	9880

23493 7590 04/28/2003

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EXAMINER
KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/680,858	BEETHAM ET AL.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on *24 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) *24 and 28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Status of the Application

1. This Office action is in response to the Amendment and Remarks filed 24 February 2003.

2. Claims 1-23 and 25-27 have been cancelled without prejudice.

3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

5. Claim 30 is objected to because of the following informalities: The phrase "a mixed duplex oligonucleotides" is not in number agreement. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 34 and 28-32 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 24 October 2002. Applicant's arguments filed 24 February 2003 have been fully considered but they are not persuasive.

Applicant argues that the present specification teaches generally that any plant gene can be modified with a MDON and that one skill in the art needs to choose a gene

and the modification desired to make the appropriate MDON (page 2, 2nd paragraph of the Remarks). This is not found to be persuasive because it is clear from the teachings of the art that one of skill in the art cannot generally modify any plant gene with a MDON.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. In the instant case, the art recognizes, as directed to modification *in situ* of plant genes using MDON's that one of skill in the art cannot correlate function based on structure of the MDON.

7. Claims 24 and 28-32 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 24 October 2002. Applicant's arguments filed 24 February 2003 have been fully considered but they are not persuasive.

Applicant argues that the present specification teaches generally that any gene can be modified with a MDON. Applicant argues that the nature of plant science methodology should not result in discrimination to plant science inventions in the Patent Office and that the fact that plant science inventions many times include time consuming steps of culturing, transforming, selecting, regenerating and progeny testing should not be used to reject claims to such inventions as being inherently non-enabling. Applicant argues that as far as one of skill in the art is concerned, the present claims are enabled and would involve mere routine experimentation to identity a gene to be changed and the corresponding MDON to change it (page 3 of the Remarks). This argument is not found to be persuasive because of the limited guidance of the specification and the amount of experimentation required to make and use the claimed invention. Applicant has provided very limited guidance on how to make and use a plant microspore comprising a mixed duplex oligonucleotide.

See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of

unpredictability of the factors involved.". In the instant case Applicant has failed to teach a high degree of predictability in the art to which the instant claims are directed.

Claim Rejections - 35 USC § 102

8. Claims 30-32 remain rejected under 35 U.S.C. § 102(a) as anticipated by Hawkes *et al* (WO 98/54330, published 3 December 1998, priority date 28 May 1997). This rejection is repeated for the reason of record as set forth in the last Office action mailed 24 October 2002. Applicant's arguments filed 24 February 2003 have been fully considered but they are not persuasive.

Applicant argues that Hawkes describes treating maize pollen with MDON and does not disclose treating microspores with MDON (page 4, 3rd paragraph of the Remarks). The Examiner concedes this argument as directed to claims 24, 28 and 29. Claims 30-32 remain rejected as directed to a product by process, and as such Applicant's arguments do not overcome the instant rejection as directed to these claims. Claims 30-32, interpreted broadly, read on microspores comprising a genomic mutation accomplished by introducing a mixed duplex oligonucleotide, such microspores are inherently disclosed by Hawkes in the regenerated plant, including Brassicas such as *Brassica napus*, which would comprise said mutation in the microspores.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claim Rejections - 35 USC § 103

9. Claims 24 and 28-32 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Kmiec (US Patent 5,731,181, filed 17 June 1996) in view of Fennell *et al* (1992, Plant Cell Reports 11:567-570). This rejection is repeated for the reason of record as set forth in the last Office action mailed 24 October 2002. Applicant's arguments filed 24 February 2003 have been fully considered but they are not persuasive.

Applicant argues that Fennell did not regenerate corn plants, studies only transient expression, used whole gene constructs and did not predict or suggest success of MDON (page 5, 1st paragraph of the Remarks). This argument is not found to be persuasive because Fennell teaches that transforming plant microspores with free DNA is advantageous to one of ordinary skill in the art, and teaches methods of delivering free DNA into a plant microspore. Kmiec teaches that the mixed duplex oligonucleotide can be introduced into a cell using a wide variety of techniques known in the art at the time of Applicant's invention including electroporation (see column 1, lines 29-33). The examiner reiterates that Brassica microspores would have been considered a functional equivalent to the maize microspores taught by Fennell as stated in the previous Office action. Applicant's example of a plant microspore comprising a mixed duplex oligonucleotide and a plant microspore which comprises a genomic mutation wherein the genomic mutation was accomplished by introducing a mixed duplex oligonucleotides into the plant microspore is prophetic and does not lead to the teaching of unexpected results (pages 27-31 of the specification). In addition, Applicant

neither claims a regenerated plant nor demonstrates a regenerated plant in the instant Application.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

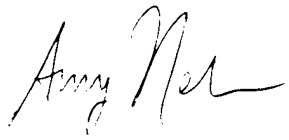
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
24 April 2003

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